

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Jeffrey W. Chambers	Examiner:	Brian E. Pellegrino
Serial No.:	10/812,250	Group Art Unit:	3738
Filed:	March 29, 2004	Docket No.:	C364.105.101
Due Date:	March 19, 2009 w/ one-month EOT		
Title:	STENT POSITIONING SYSTEM AND METHOD		

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on December 19, 2008, appealing the final rejection of claims 28-45 of the above-identified application as set forth in the Final Office Action mailed September 19, 2008.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of \$270.00 for filing a Brief in Support of an Appeal (as set forth under 37 C.F.R. §41.20(b)(2)). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 28-45.

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REAL PARTY IN INTEREST

The real party in interest is Jeffrey W. Chambers, MD, of Maple Grove, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellant is unaware of other prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

STATUS OF CLAIMS

In the Final Office Action dated September 19, 2008, claims 28-45 were rejected. Claims 28-45 remain pending in the application. Claims 1-27 were previously cancelled. Claims 28-45 are the subject of the present Appeal.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Office Action mailed September 19, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Discussions about features of claim 1 can be found *at least* at the cited locations in the specification and drawings.

Claim 28 relates to a method of deploying an intravascular stent 216 within a patient (Paragraphs [0063]-[0072]. The method includes delivering a distal end 222 of a guiding catheter 210 adjacent an ostium 251 of a vessel 252 to be stented (Paragraphs [0063]-[0064] and Fig. 19A). A deployment site locator 212 is guided in a collapsed state through the delivered guiding catheter 210 (Paragraph [0064]). The deployment site locator 212 includes a base 232 and a plurality of rods 230 affixed to the base 232 (Paragraph [0050]-[0051] and Fig. 16).

The plurality of rods 230 are extended from the distal end of the delivered guiding catheter 210 such that the plurality of rods 230 transition from the collapsed state to an expanded

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state in which the plurality of rods 230 expand relative to one another to collectively define a maximum outer dimension greater than a maximum dimension of the ostium (Paragraph [0065] and Fig. 19B).

A position of the ostium 251 is determined by contacting bodily structures 254 of the patient apart from the vessel 252 and immediately proximate the ostium 251 with at least one of the plurality of rods 230 and the deployment site locator 212 in the expanded state (Paragraph [0065]).

The stent 216 is delivered through the guiding catheter 210 to a desired stent location (Paragraph [0066] and Fig. 19C). The desired stent location is based upon the determined position of the ostium (Paragraphs [0067]-[0069]). The stent 216 is deployed at the desired stent location (Paragraph [0070] and Fig. 19D). The deployment site locator 212 is withdrawn from the patient (Paragraph [0072] and Fig. 19E).

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GROUND OF REJECTION TO BE REVIEWED ON APPEAL

- I. Whether claims 28-30, 32, and 34-45 were properly rejected under 35 U.S.C. §103(a) as being obvious over Saltiel, U.S. Patent No. 6,458,151 (“Saltiel”) in view of Zikorus et al., U.S. Publication No. 2002/68866 (“Zikorus”).
- II. Whether claim 31 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Saltiel in view of Zikorus, and further in view of Close et al., U.S. Patent No. 6,532,380 (“Close”).
- III. Whether claim 33 was properly rejected under 35 U.S.C. §103(a) as being obvious over Saltiel in view of Zikorus, and further in view of Shaknovich, U.S. Patent No. 5,749,890 (“Shaknovich”).

ARGUMENT

I. Applicable Law

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. *MPEP* §2141. The examiner bears the burden under 35 U.S.C. §103 in establishing a *prima facie* case of obviousness. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some additional rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 USPQ2d 1385, 1396 (U.S. 2007); *In re Khan*, 78 USPQ2d 1329 (Fed. Cir. 2006). In this regard, identification of a teaching, suggestion, or motivation for modifying a reference or combination of the teachings of multiple references provides helpful insight. *KSR* at 1396. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Leapfrog Enterprises, Inc. v. Fischer-Price, Inc.*, 82 USPQ2d 1687, 1690-1691 (Fed. Cir. 2007). A prior patent cited as a §103 reference must be considered in its entirety, “i.e., as a whole,

including portions that lead away from the invention.” *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). That is, the Examiner must recognize and consider not only the similarities, but also the critical differences between the claimed invention and the prior art as one of the inquiries pertinent to any obvious inquiry under 35 U.S.C. §103. *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

II. REJECTION OF CLAIMS 28-30, 32, AND 34-45 UNDER 35 U.S.C. §103(a) AS BEING UNPATENTABLE OVER SALTIEL IN VIEW OF ZIKORUS

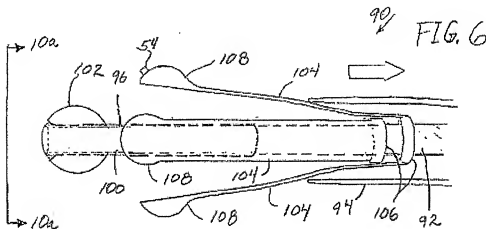
Claims 28-30, 32 and 34-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Saltiel, US Patent No. 6,458,151 in view of Zikorus et al., US Patent Publication No. 2002/0068866.

In support of this rejection, the Examiner cited Saltiel for disclosing many of the elements in the claimed method but acknowledged that Saltiel fails to disclose a site locator having a plurality of rods to the location to be treated. The Examiner cited Zikorus for disclosing this element and claimed it would have been obvious to modify Saltiel to include the structure from Zikorus.

In the Response to Arguments section, the Examiner indicates that “the structure of Zikorus is only being incorporated into the method of delivering a stent as disclosed by Saltiel and that Saltiel discloses the deployment site locator is expanded prior to deployment of the stent and contacts bodily structures of the patient, col. 2, lines 26,27. Thus, the steps would be followed by Saltiel’s method of delivering a stent, but just uses alternatively an expandable rod system.”

There are two components from Zikorus that could be considered relevant to the plurality of rods set forth in the claimed method – the electrodes and the hook-shaped guide wire.

The electrodes are illustrated in Fig. 6 of Zikorus that is reproduced below. It is noted that many of the reference numerals used in the figures in Zikorus are not used in the specification of this document.



While Zikorus discloses a system in which four electrodes are slidably movable with respect to a guiding catheter such that when the electrodes emerge from the guiding catheter they expand away from each other, the Examiner cannot ignore the overall structure of Zikorus and the operation of the electrodes in such a system when combining such elements with Saltiel to allegedly produce the claimed structure.

As set forth in Paragraph [0029] of Zikorus, “the primary electrodes 58 are moved by the primary leads outward relative to the axis defined by the outer sheath, while the central secondary electrode 59 remains substantially linear along the axis defined by the outer sheath. The primary leads continue to move outward until the electrodes are placed in apposition with the vein wall and the outward movement of the primary leads is impeded. The primary electrodes 58 contact the vein wall along a generally circumferential area or band of the vein wall.” (emphasis added)

As discussed in Zikorus, the electrodes 58/108 provide a thermal effect which causes the venous tissue to shrink to thereby reduce the diameter of the vein. The shrinking vein wall presses the primary lead electrodes together to a reduced profile shape which is sufficiently small so that the vein is effectively ligated.

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Nowhere in Zikorus is it taught or suggested that the electrodes 58/108 are used as part of a deployment site locator where ends of the rods in the expanded state define a maximum outer dimension that is greater than a maximum dimension of the ostium which enables a position of the ostium to be determined by contacting bodily structures of the patient apart from the vessel and immediately proximate the ostium with at least one of the plurality of rods and the deployment site locator in the expanded state.

Because of the significant differences between the disclosures in Zikorus and Saltiel, it is submitted that a person of ordinary skill in the art would not appreciate that Saltiel could be modified to include a deployment site locator having a base and a plurality of rods affixed to the base. Accordingly, the claimed method is not obvious when viewed in light of Saltiel and Zikorus.

The hook-shaped guide wire is illustrated in Fig. 8 of Zikorus that is reproduced below.

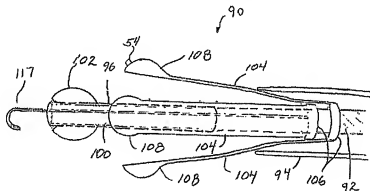


FIG. 8

As discussed in Zikorus, the hook-shaped tip 117 is attached to an end of the guide wire. Such a structure is separate from the electrodes that are attached to inner sheath 92 as Zikorus describes these two components as being separately movable.

The claimed structure indicates that the deployment site locator includes a base and a plurality of rods affixed to the base. Accordingly, there is no support for the Examiner's contention that "the hook can be considered part of the "plurality of rods" and this interpretation

of Zikorus would not meet the claimed structure because the hook-shaped tip 117 is separate from the electrodes.

Additionally, the Zikorus device operates in a very different manner than the claimed invention. The Zikorus device is retained in a fixed position with respect to the sapheno-femoral junction by hooking the guide wire to the sapheno-femoral junction.

In contrast, the claimed method utilizes a plurality of expanded rods that collectively define a maximum outer dimension that is greater than a maximum dimension of the ostium. Rather than hooking onto the ostium, the claimed method causes at least one of the rods in the expanded state to contact bodily structures of the patient apart from the vessel and immediately proximate the ostium. Because of this significantly different mechanism of action, there is no support for the Examiner's proposed combination of the references.

In view of the preceding comments, it is submitted that independent claim 28 is not obvious when viewed in light of Saltiel and Zikorus. Claims 29-30, 32 and 34-45 depend from independent claim 28 and, as such, are also not obvious. Reconsideration and withdrawal of the rejection of claims 28-30, 32 and 34-45 are respectfully requested.

III. REJECTION OF CLAIM 31 UNDER 35 U.S.C. §103(a) AS BEING UNPATENTABLE OVER SALTIEL IN VIEW OF ZIKORUS AND CLOSE

Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Saltiel in view of Zikorus and Close et al., US Patent No. 6,532,380.

After acknowledging that "Saltiel in view of Zikorus do not state that x-ray imaging is used for adjusting the position of the stent," the Examiner cites Close for disclosing the use of x-ray imaging in the placement of a stent. The Examiner then contends that it would have been obvious to combine the references to produce the claimed method.

Shaknovich does not overcome the deficiencies set forth above with respect to the combination of Saltiel and Zikorus. As such, the combination of Saltiel, Zikorus and Shaknovich does not render claim 31 obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. REJECTION OF CLAIM 33 UNDER 35 U.S.C. §103(a) AS BEING UNPATENTABLE OVER SALTIEL IN VIEW OF ZIKORUS AND SHAKNOVICH

Claim 33 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Saltiel in view of Zikorus and Shaknovich, US Patent No. 5,749,890.

After acknowledging that “Saltiel in view of Zikorus do not explicitly state the coronary artery and the aorta wall is of the ostium where the position of the stent is done,” the Examiner contends that “Shaknovich teaches that the target vessel to be stented is the coronary artery and the vascular structure proximate the ostium is the aorta wall.” The Examiner then contends that it would have been obvious to combine the references to produce the claimed structure.

Shaknovich does not overcome the deficiencies set forth above with respect to the combination of Saltiel and Zikorus. As such, the combination of Saltiel, Zikorus and Shaknovich does not render claim 33 obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

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CONCLUSION

Appellant submits that the Examiner has presented the best available references against the claimed subject matter of the pending application. Reversal of the rejections of claims 28-45 is respectfully requested.

Any inquiry regarding this Appeal Brief should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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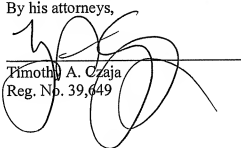
Respectfully submitted,

Jeffrey W. Chambers,

By his attorneys,

Date: _____
TAC:jms

March 19, 2009



Timothy A. Czaja
Reg. No. 39,649

CLAIMS APPENDIX

1. – 27. (Cancelled)

28. A method of deploying an intravascular stent within a patient, the method comprising:
- delivering a distal end of a guiding catheter adjacent an ostium of a vessel to be stented;
 - guiding a deployment site locator in a collapsed state through the delivered guiding catheter, the deployment site locator including a base and a plurality of rods affixed to the base;
 - extending the plurality of rods from the distal end of the delivered guiding catheter such that the plurality of rods transition from the collapsed state to an expanded state in which the plurality of rods expand relative to one another to collectively define a maximum outer dimension greater than a maximum dimension of the ostium;
 - determining a position of the ostium by contacting bodily structures of the patient apart from the vessel and immediately proximate the ostium with at least one of the plurality of rods and the deployment site locator in the expanded state;
 - delivering a stent through the guiding catheter to a desired stent location, wherein the desired stent location is based upon the determined position of the ostium;
 - deploying the stent at the desired stent location; and
 - withdrawing the deployment site locator from the patient.
29. The method of claim 28, wherein the stent is fixed relative to the deployment site locator such that the stent is delivered at a fixed distance from the deployment site locator to the desired stent location following determination of the position of the ostium.
30. The method of claim 28, wherein delivering the stent to the desired stent location includes determining the position of the stent and the deployment site locator by a visual indication and adjusting the position of the stent relative to the deployment site locator such that the stent is delivered to the desired stent location.

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31. The method of claim 30, wherein the visual indication includes x-ray imaging.
32. The method of claim 30, wherein adjusting the position of the stent relative to the deployment site locator includes visually confirming that at least one radio-opaque marker associated with the stent is aligned with at least one radio-opaque marker associated with the deployment site locator.
33. The method of claim 28, wherein the vessel to be stented is a coronary artery and the vascular structures proximate the ostium include an aorta wall.
34. The method of claim 28, wherein the desired stent location is such that a proximal end of the stent is located at the ostium of the vessel to be stented.
35. The method of claim 28, further comprising delivering a guide wire into the vessel to be stented via the guide catheter, and wherein guiding the deployment site locator through the guide catheter includes guiding the deployment site locator over the guide wire to the ostium of the vessel to be stented.
36. The method of claim 35, wherein delivering the stent includes guiding a stent delivery device over the guide wire and through the deployment site locator into the vessel to be stented.
37. The method of claim 28, wherein each one of the plurality of rods is configured to extend outward radially to contact the vascular structures proximate the ostium.
38. The method of claim 28, wherein extending the plurality of rods from the distal end of the guide catheter further includes transitioning the deployment site locator from a collapsed state to an expanded state, and further wherein the expanded state includes a distal portion of

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each of the plurality of rods being spaced substantially farther away from one another than in the collapsed state.

39. The method of claim 38, wherein the plurality of rods extend away from one another in the expanded state and are substantially parallel in the collapsed state.

40. The method of claim 38, wherein transitioning the deployment site locator from a collapsed state to an expanded state is accomplished via spring action by loading and unloading the plurality of rods.

41. The method of claim 38, wherein the stent remains in the desired location upon withdrawing of the deployment site locator from the patient.

42. The method of claim 28, wherein the step of extending the plurality of rods occurs prior to placement of the stent within the vessel to be stented.

43. The method of claim 28, wherein each of the rods extends from the base to a free end opposite the base to define an intermediate segment between the base and the free end, and further wherein contacting bodily structures immediately proximate the ostium includes the intermediate segment of at least one of the rods contacting the bodily structure immediately proximate the ostium.

44. The method of claim 43, wherein contacting bodily structures further includes the at least one rod deflecting radially outwardly in response to contacting of the corresponding intermediate segment with the bodily structure.

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45. The method of claim 44, wherein following initial contact of the at least one rod with the bodily structure, continued movement of the base toward the ostium causes the corresponding free end to displace radially outwardly.

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EVIDENCE APPENDIX

All the evidence related to this Appeal is on the record and before the Board. Therefore, no additional evidence is identified in this Appendix.

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RELATED PROCEEDINGS APPENDIX

There are no additional related proceedings to be considered in this Appeal. Therefore, no such proceedings are identified in this Appendix.